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Use of omalizumab in pediatric patients with uncontrolled severe allergic asthma. Inflammatory markers and clinical evolution. A 10 years reflection of its use
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Introduction
Omalizumab is a recombinant humanized anti-IgE monoclonal antibody that has been shown to be an effective add-on therapy for patients with uncontrolled severe allergic asthma (USAA). The purpose of the study was to describe the clinical course and inflammatory markers in this group of patients after one year of treatment with omalizumab.

Methods
Observational and retrospective study in children diagnosed as severe uncontrolled allergic asthma who received treatment with omalizumab in the last 10 years, analyzing inflammatory markers, lung function, treatment step, oral corticosteroid cycles and number of admissions before and after the first year of treatment. For this purpose, the patients were divided into three groups: 1) all USAA patients included, 2) USAA patients with respiratory sensitization and 3) USAA patients with respiratory sensitization and food allergy.

Results
A total of 48 patients were identified, 30 were male, the mean age at initiation of omalizumab was 9.8 ± 4 years. A 79% were diagnosed as USAA patients with respiratory sensitization and another 21% as USAA patients with respiratory sensitization and food allergy. Before treatment there was no correlation between peripheral eosinophils and induced sputum eosinophils value (p=0.7). Analyzing all the patients together (first group) after one year of treatment, there were significant changes with a decrease in: exhaled nitric oxide fraction (FeNO): (difference of means: 7.65; 95% CI [0.56 to 14.7], p=0.035), treatment step:(difference of means: 0.85, 95% CI [0.57 to 1.12], p<0.001), oral corticosteroid cycles: (difference of means: 3; 95% CI [2.3 to 3.7], p<0.001), number of annual admissions: (difference of means: 0.3; 95% CI [0.08 to 5.8], p=0.010) and IgE: (difference of means: -417; 95% CI [-656 to -178], p=0.001); there were no differences in: serum eosinophils (p=0.96) or in pulmonary function (p=0.198). In USAA children with only respiratory sensitization the same results were obtained. Nevertheless in the group of USAA patients with respiratory sensitization and food allergy, we found differences of means showing greater treatment step, more cycles of oral corticosteroids and higher IgE values without achieving statistically significant differences.

Conclusions
After one year of treatment, omalizumab already decreases the need for cycles of oral corticosteroids, number of admissions for asthma exacerbations and FeNO significantly. These results suggest that the response to omalizumab is better evaluated by clinical parameters rather than inflammatory markers. Finally it is likely that patients who associate respiratory sensitization and food allergy have a worse outcome than those with only respiratory.